JUN 1 3 2001

K011103

Summary of Safety & Effectiveness:

1. **BD Contact Person:**

Greg Morgan
Head of Regulatory Compliance
BD Medical
BD
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Franklin Lakes, NJ
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2. **Device Name:** BD Spring Based Syringe
3. **Predicate Devices:** BD Single-Use Syringe
4. **Product Description/Function:**

4.1 Description: Single-use syringe with a needle protection system. Needle sizes:18G-25G, Syringe sizes: 3mL – 10mL.

4.2 Function: Product is used for aspiration/injection of fluids. The device contains a mechanism that encapsulates the needle after use. In the activated position the needle is completely enclosed inside the syringe to guard against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

5. **Comparison of Modified & Predicate Devices:**

5.1 Descriptive Comparison to a Legally Marketed Device
The BD Spring Based Syringes can be used in the same fashion as standard BD Single-Use syringes. When the BD Spring Based Syringe is in the "ready-to-use" position it provides the same usable injection needle length and same barrel scale markings as a standard syringe and hypodermic needle.

Comparison has been made to the BD Single Use Syringe. The BD Spring Based Syringe is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin. The BD Spring Based Syringe has a detachable needle with a dedicated fitting. The dedicated interface prevents the clinician from attaching the BD Spring Based Syringe components to a standard syringe or needle.

The BD Spring Based Syringe contains a tool used to cut through the stopper and inner hub allowing the needle to become retracted inside the plunger rod of the syringe after use. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

5.2 Material Changes: There are no significant changes in the materials used for the BD Spring Based Syringe

5.3 Manufacturing Process Changes: The manufacturing processes are being modified to assemble the components associated with the BD Spring Based Syringe.

5.4 Manufacturing Site Changes: No new manufacturing site is being utilized.

5.5 Packaging Component Changes: The package design is being modified to accept the size of the BD Spring Based Syringe.

6. Equivalence:

The BD Spring Based Syringe was compared to the predicate devices using the following criteria: shield removal, cannula removal, stopper breakout and sustaining force, hub and stopper leakage, hub strip torque, hub disconnection force, activation forces, plunger rod separation, hub separation and impact resistance. The BD Spring Based Syringes performed in a similar manner to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 2001

Mr. Greg W. Morgan
Head of Regulatory Compliance
BD Medical Systems
1 Becton Drive MC 226
Franklin Lakes, New Jersey 07417

Re: K011103
Trade/Device Name: BD Spring Based Syringe
Regulation Number: 880.5860
Regulatory Class: II
Product Code: MEG and FMF
Dated: April 10, 2001
Received: April 11, 2001

Dear Mr. Morgan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use: K011103

The BD Spring Based Syringe is used for general purpose injection and aspiration of fluid from vials, ampoules and parts of the body below the surface of the skin except phlebotomy. The BD Spring Based Syringe has a detachable needle with a dedicated fitting. The dedicated interface prevents the clinician from attaching the BD Spring Based Syringe components to a standard syringe or needle.

The BD Spring Based Syringe contains a tool used to cut through the stopper and inner hub allowing the needle to become retracted inside the plunger rod of the syringe after use. After activation the needle is fully contained inside the syringe guarding against accidental needle sticks during normal handling and disposal of the used needle/syringe combination.

Patricia Cucuzza

(Division Sign-Off)
Division of Dental, Infection Control,
General Hospital Devices
Number K011103